Safety and Effectiveness Summary

Demonstration of safety and effectiveness is based on large part on Bentec Medical past history with the Biliary Stent products. Since the start of manufacture of Biliary Stents by Bentec Medical in 1994 only one functional product complaint has been received in 1995. Bentec Medical does not have historical data on the accessories at this time. Since the accessories are being purchased as legally marketed devices from other manufacturers we believe that these accessories are both safe and effective when used for their intended purposes.

1. Configuration – The Biliary Stent Kits are designed to facilitate the procedure of inserting or replacing the Biliary Stents presently used in the hospitals by incorporating other accessories that are normally used in the procedure. Although this is new package for Bentec Medical several manufacturers are presently selling the components used in the kits. Bentec Medical will continue to produce the Biliary Stent and will purchase the same components presently available in the market to incorporate them in the Biliary Kits.

2. Physicals – The Biliary Stents to be incorporated in the Kits are identical to the predicate Biliary Stents presently being marketed by Bentec Medical. The physical properties of the raw material meet the raw materials manufacturer claims. This has been confirmed by physical testing of the product.

3. Material – No changes in materials or processing have been made to the Biliary Stents. Confirmation will be in the form of documentation on file for the products.

4. Labeling – Labeling has been modified to include the components of the kits no new or additional claims are being made in the use of the product. The labels will include all regulatory requirements. The product information data sheet will be modified to provide information on the proper use of the accessories provided in the package.

5. Packaging – Packaging will be done in pouches with a Tyvek® backing. A reinforcing board to maintain the dilator free of kinks will be inserted in the package. Units will be sold individually and in packages of 10. The present predicate device is also packaged in Tyvek®. The major change will be size of the pouch that will be larger for the proposed products in order to accommodate the accessories in the package.

6. Summary – in summary this 510k request covers the kitting of presently marketed devices into one package. No additional claims or changes in product or usage are being made by this request. As a new product family for Bentec Medical these product are being developed using the design control guidelines that are in effect as part of our Quality System. A design history file

has been created for these product lines and is a permanent record maintained at our facility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 6 2001

Mr. David Tucker
Director of Operations
Bentec Medical, Inc.
1380 East Beamer Street
P.O. Box 1553
Woodland, CA 95776-1553

Re: K002650
Trade Name: Biliary Kits and Accessories
Dated: November 18, 2000
Received: November 21, 2000
Regulatory Class: II
21 CFR §876.5010/Procode: 78 FGE

Dear Mr. Tucker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

In addition, we have determined that your device kit contains Surgilube, which is subject to regulation as a drug.

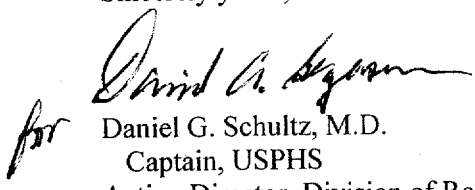
Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

Ver/ 3 - 4/24/96

Applicant: **Bentec Medical**

510(k) Number (if known): K002650

Device Name: **Biliary Kits and Accesories**

Indications For Use:
Percutaneous biliary drainage with the Biliary Stent is utilized for the management of both benign and malignant biliary obstructions. The Stent is used to prevent or relieve sepsis, to relieve symptoms of obstruction such as pruritis and to maintain a pathway for bile flow into the bowel for digestive function. The Stent is indicated for malignant biliary obstruction, such as primary bile duct or biliary tract carcinoma, pancreatic carcinoma, metastases to the porta hepatis and other malignant conditions causing obstructive jaundice. The Stent can also be used in cases of benign biliary obstructions such as structures secondary to primary or iatrogenic trauma pancreatitis, biliary calculi or biliary leaks.
The Silicone Biliary Stent is used in percutaneous management of Benign Biliary Strictures. The procedure is normally referred to as Percutaneous Transhepatic Cholangiography/Percutaneous Biliary Drainage (PTC/PBD).
Biliary Stent are replaced at regular intervals as required and at the attending physician recommendations. Bentec Medical will label the Biliary Stent replacement guideline at every 4 weeks.
Each of the components of the kit may be packaged and sold independently.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)(Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002650

Prescription Use ✓
(Per 21 CFR 801.109)